Kazia Therapeutics

Rebranding to Kazia

GDC-0084 Phase II to begin shortly

Pharma & biotech

Novogen has changed its name to Kazia Therapeutics and undertaken a 10:1 share consolidation following shareholder approval in November. It has also out-licensed its preclinical super-benzopyran development program, and has added a dose optimization lead-in component to the Phase II trial of GDC-0084 in glioblastoma, which is expected to commence in early 2018. Although the more focused pipeline and longer Phase II trial for GDC-0084 prompts us to trim our valuation to between $53m and $96m, we believe the changes will be positive in the long run, increasing the chance of success in the GDC-0084 development program.

Year end	Revenue (US$m)	PTP (US$m)	EPADR ($)	DPADR ($)	P/E (x)	Gross Yield (%)
06/16	2.9	(9.2)	(2.25)	0.0	N/A	N/A
06/17	6.8	(8.6)	(1.80)	0.0	N/A	N/A
06/18e	3.1	(9.6)	(1.99)	0.0	N/A	N/A
06/19e	10.7	(5.0)	(1.03)	0.0	N/A	N/A

Note: Converted at A$1/US$0.76 for the table above and throughout the note.

GDC-0084 Phase II to start early in the new year

Kazia is on track to initiate a Phase II study of its oral PI3K inhibitor GDC-0084 in glioblastoma early in the new year. It has received its first ethics committee approval and the US site will open for recruitment in early 2018. The trial design now includes a lead-in component to optimize dosing before the randomized study begins. Identifying an optimized dosing regimen would be likely to increase the prospects of success for the Phase II study, which compensates for the extra 12-15 months it is expected to add to the overall Phase II program. The open-label lead-in should provide an initial data readout in late 2018 or early 2019.

GDC-0084 is targeting an unmet need in glioblastoma

The trial will test GDC-0084 in a subset of glioblastoma patients who are known to obtain little benefit from standard temozolomide chemotherapy. The clear unmet need in this patient group could open access to accelerated approval pathways.

Phase I Cantrixil data in 2018

Kazia is expected to report the maximum tolerated dose (MTD) from the Phase I ovarian cancer study of Cantrixil in Q118. Potential efficacy signals from a 12-patient expansion cohort at the MTD are expected to read out later in 2018.

Valuation: Revised to $53-96m in two scenarios

We have reduced our indicative valuation range to $53-96m or $10.88-19.89 per ADR (vs $66-108m, $13.70-22.32 per ADR), under either post-Phase III approval or accelerated approval scenarios for GDC-0084. The valuation changes reflect removal of the out-licensed preclinical Trilexium (super-benzopyran) program and later forecast launch dates for GDC-0084 and Cantrixil. Kazia had $11.5m cash at 30 June 2017, which we forecast will be sufficient to fund operations into FY19, by which time preliminary Cantrixil data are likely to read out. We estimate that the company may require $5m of additional funding in FY19.

21 December 2017

Price	**$2.50**
Market cap	**$12m**
	ADR/Ord conversion ratio 10/1
Net cash ($m) at 30 June 2017	11.5
ADRs in issue	4.8m
ADR Code	KZIA
ADR exchange	NASDAQ
Underlying exchange	ASX
Depository	BNY

ADR share price performance

52-week high/low	$7.16	$2.40

Business description

Kazia Therapeutics is an ASX- and NASDAQ-listed biotechnology company. It is developing the PI3K/mTOR inhibitor GDC-0084 for brain cancer and Cantrixil for ovarian cancer. GDC-0084 was in-licensed from Genentech in late 2016.

Next events

Initiate GDC-0084 Phase II	Q118
Cantrixil Phase I MTD identified	Q118
Cantrixil Phase I efficacy data	2018

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Name change, share consolidation

On 15 November shareholders voted to rebrand Novogen to Kazia Therapeutics, and approved a consolidation of ASX-listed common stock at a 10:1 ratio. At the same time the ADR ratio was changed so that the number of ADRs on issue is unchanged.

The change of name reflects the company's revised strategy to develop a portfolio of clinical-stage pharmaceutical assets by identifying high-potential, clinical-stage programs in pharmaceutical companies. The company aims to adopt these programs and demonstrate their potential through focused development work, then partner them with other companies for commercialization. The in-licensing of GDC-0084 from Genentech in 2016 is an example of this strategy.

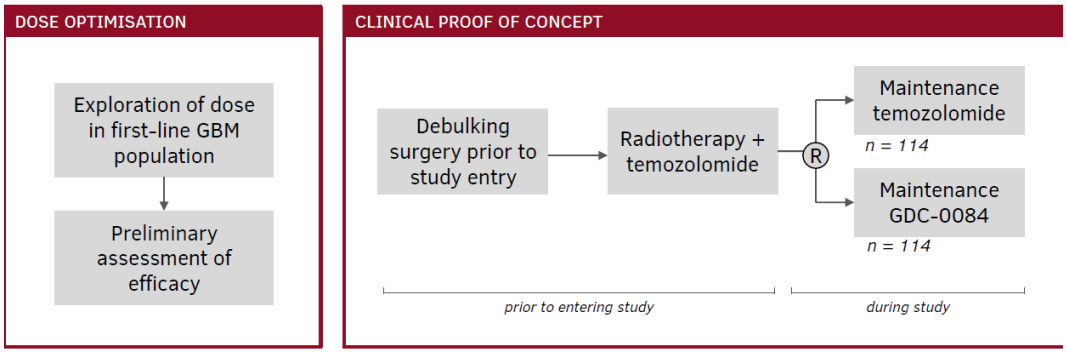
GDC-0084 Phase II to start early in the new year with a dose optimisation component

Kazia expects to initiate a Phase II clinical study of GDC-0084 in early 2018 in patients with recently diagnosed glioblastoma (GBM), an aggressive brain cancer. The company recently received its first ethics committee approval from the Western Institutional Review Board in the United States, and the planned first site for the study is expected to be open for recruitment in early 2018. The study drug has been formally released by its manufacturers and is now ready to be shipped to trial sites.

The study design has been refined to include a lead-in component, which aims to optimize dosing in the target patient population (Exhibit 1). The lead-in component will allow an earlier preliminary efficacy readout about 12-15 months after commencing the trial. The trial design was finalized in consultation with Kazia's clinical advisors after a constructive meeting with the US FDA in September.

As previously announced, the randomized component of the Phase II study will compare maintenance therapy with GDC-0084 vs standard-of-care temozolomide (TMZ) in recently diagnosed GBM patients who have undergone standard therapy of surgery to remove the bulk of the tumor and a course radiation therapy (XRT) combined with TMZ. After completing XRT, 228 patients will be randomized to receive maintenance therapy with either GDC-0084 or TMZ to treat residual tumor cells and delay recurrence of the disease. The study will target the 61% of GBM patients where tumor cells have an unmethylated MGMT promoter, as these patients receive only minimal benefit from treatment with TMZ and are in urgent need of more effective therapies.

Exhibit 1: Revised GDC-0084 Phase II design includes a lead-in study



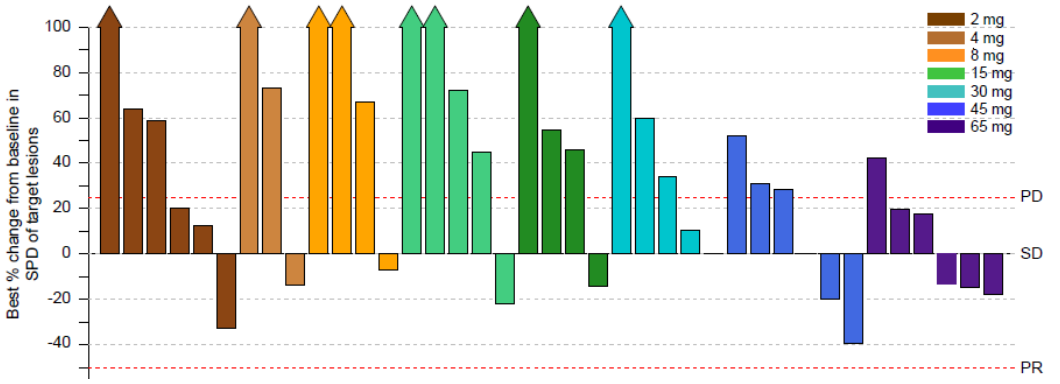
Source: Kazia 2017 AGM presentation

Genentech has previously investigated GDC-0084 in a Phase I study in very sick patients with late-stage disease and rapidly growing tumors, whereas Kazia intends to conduct the Phase II study in the first-line setting. These recently diagnosed patients would be expected to be in better overall health, and may tolerate a higher dose of GDC-0084. The lead-in component will test higher doses

and may also allow the company to investigate different dosing regimens. In Genentech's Phase I study the maximum tolerated dose (MTD) was identified as 45mg administered by once-daily oral dosing. Kazia could also explore whether alternative regimens such as dosing every second day or four days on, three days off improved tolerability.

Exhibit 2 summarizes the tumor responses for the patients in Genentech's Phase I study of GDC-0084, grouped by dose cohort. Although none of the patients reached the 50% reduction in tumor size that would qualify as a partial response, a dose response in tumor growth was apparent, with much less tumor growth in patients treated at 45mg (the MTD) or higher doses. The dose response shown in Exhibit 2 provides encouragement that a higher dose of GDC-0084 may improve efficacy, which would increase the overall chance of success in the Phase II study.

Exhibit 2: GBM patients in Phase I trial showed a trend to better disease control at higher doses of GDC-0084



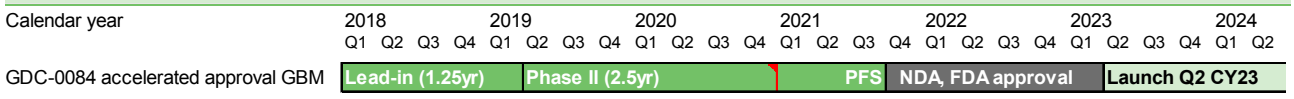
Source: Wen et al 2016 ASCO poster. Note: Maximum tolerated dose was identified as 45mg (blue bars).

GDC-0084 development timelines extended by about a year

We have revised our forecast timelines for two potential development scenarios for GDC-0084 in GBM to include the lead-in stage of the Phase II study. While the lead-in study will provide an earlier first look at efficacy in this patient setting, the later start to the randomized component of the Phase IIb study means that the top-line efficacy readout from Phase IIb is likely to be delayed by 15-18 months compared to our previous assumptions.

Exhibit 3 shows that in a potential scenario where GDC-0084 gains accelerated approval in GBM after demonstrating a statistically significant and clinically meaningful improvement in PFS, we now assume a potential market launch in Q2 CY23 (vs Q4 CY21 previously).

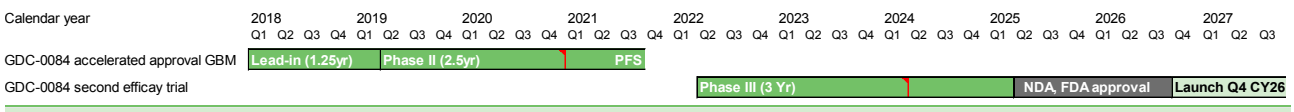
Exhibit 3: Assumed clinical trial and timeline for GDC-0084 accelerated approval



Source: Edison Investment Research

Under our second scenario, which assumes that the results of the first Phase II trial indicate that GDC-0084 is efficacious against GBM, but that additional evidence from a second clinical trial is required before filing for approval, we now forecast a potential market launch in Q4 CY26 (vs Q2 CY25 previously).

Exhibit 4: Assumed clinical trial and approval timeline for GDC-0084 under two-trial scenario



Source: Edison Investment Research

Out-licensed preclinical benzopyran program to Heaton-Brown Life Sciences

As part of its strategy to focus on clinical development programs, Kazia has out-licensed its preclinical super-benzopyran and ad-het programs, including Trilexium, to Heaton-Brown Life Sciences (HBLS). Kazia will retain a commercial interest in the preclinical assets, through a 10% shareholding in HBLS plus milestone and royalty payments linked to successful development of the intellectual property.

Kazia retains all rights relating to Cantrixil, and the agreement prevents the development of Trilexium as a therapy for ovarian cancer.

HBLS is a newly formed private company established by Dr Andrew Heaton and Dr David Brown, who are both former employees of Kazia and co-founders of the Triaxial technology that underpinned the super-benzopyran and ad-het programs. HBLS does not yet have the financial resources to pursue clinical development of the super-benzopyran program.

A key benefit from the transaction is that it allows Kazia to focus its resources on its clinical-stage programs, and will reduce expenditure on preclinical programs.

Cantrixil Phase I is expected to identify MTD in Q118

The Phase I study of the super-benzopyran drug Cantrixil in ovarian cancer, which commenced in December 2016, is expected to report the maximum tolerated dose (MTD) in Q1 CY18; previous guidance had been that the MTD could read out in H2 CY17 or H1 CY18. Once the MTD has been identified, an expansion cohort of 12 additional ovarian cancer patients will be treated at the MTD. A readout of potential efficacy signals is expected later in CY18.

Valuation

We have revised our valuation model for Kazia to reflect the out-licensing of Trilexium and the other preclinical super-benzopyran assets to Heaton-Brown Life Sciences, and longer development timelines for GDC-0084 and Cantrixil.

We have valued GDC-0084 under two different development scenarios for GBM – in addition to our base case valuation, which assumes market launch in 2026 following completion of a Phase III trial, we have valued GDC-0084 assuming accelerated approval with a launch in 2023. We have:

- removed Trilexium from our valuation model. Although Kazia retains an economic interest in the super-benzopyran technology, Heaton-Brown Life Sciences does not yet have the resources to fund clinical development, resulting in a lack of visibility regarding the future development path for the technology;
- deferred GDC-0084 launch date to 2023 under the early approval scenario and to 2026 under post-Phase III approval, vs previous assumptions of launches in 2021 and 2025 respectively;
- reduced forecast near-term spending on the GDC-0084 clinical trial, pushing back part of the trial costs to FY21 vs the previous assumption of trial completion in FY20;
- deferred Cantrixil launch by six months to H2 CY25;
- rolled forward DCF model; and
- adjusted the share count to reflect the 1 for 10 consolidation of ordinary shares (the NASDAQ ADR ratio has been changed from 100:1 to 10:1, so the number of ADRs in issue has not changed).

As a result of these changes, our base case valuation of Kazia has declined to $53m (previously $66m) or $10.88/ADR undiluted (vs $13.70 per ADR) and $10.34/ADR after diluting for options and

convertible notes. Kazia's primary listing is on the ASX under the code KZA; each NASDAQ-listed ADR represents 10 ordinary shares following the 10:1 consolidation in November (the number of ADR's on issue remains unchanged). Our undiluted base case valuation equals A$1.43 per ASX-listed ordinary share at current exchange rates. Note that the per-share value accounts for the shares issued as part of the acquisition of Glioblast ($1.2m in shares) but not the Glioblast milestone payments (potentially $1.0m of shares in FY18 on initiation of Phase II, and a further $1.0m potentially payable in FY21 on successful completion of Phase II).

Our base case valuation assumes that GDC-0084 is out-licensed to a marketing partner in 2021 after reporting PFS data from the Phase II trial, in a deal that includes $20m upfront and $120m in clinical and regulatory milestone payments. We also assume that Kazia pays a royalty of 10% of net sales to Genentech and that global sales for GBM reach $1,050m in 2030.

Our valuation is based on a risk-adjusted discounted cash flow model. Our cash flow forecasts extend out to 2035, but do not include any terminal valuation and apply a 12.5% discount rate. In calculating the diluted NPV/share, we assume that the $0.5m remaining balance of the Triaxial convertible note is converted to 2.4m shares on completion of Phase II trials (the $1.2m convertible note was issued as part of the purchase of Triaxial and its SBP technology, $0.7m was converted in H117).

Exhibit 5 shows our base case market assumptions for GDC-0084 and Cantrixil and the contribution of product royalties and milestone payments to the rNPV. We have offset the risk-adjusted trial cost against milestone revenue for each drug, rather than against royalty revenue. This understates the contribution of the milestone payments to the rNPV and overstates the contribution of royalties.

Exhibit 5: Kazia base case valuation (assumes confirmatory GDC-0084 pivotal trial required)

	Likelihood (%)	rNPV ($m)	rNPV/ ADR ($)	Assumptions
GDC-0084 – GBM	25%	11.7	2.42	Global peak sales* of $1,050m from GBM (11,500 US cases/year, 61% unmethylated MGMT promoter, 80% penetration); pricing of $50k. Global sales 2x US sales; launch 2026; assumes receives 15% royalty on sales, pays away 10% of royalty to Genentech.
GDC-0084 – brain metastases in HER2+ breast cancer	20%	4.9	1.01	Global peak sales of $570m (233,000 US breast cancer cases/year, 37% HER2+, 7% develop brain metastases, 50% penetration); pricing of $50k. Global sales 2x US sales; launch 2026; assumes receives 15% royalty on sales, pays away 10% of royalty to Genentech.
Ovarian and other abdominal cancers: Cantrixil	10%	18.8	3.89	Global peak sales of $680m from ovarian cancer (14,300 US deaths/year, 30% penetration) and bowel cancer (50,300 US deaths, 25% develop malignant ascites, 20% penetration); pricing of $50k. Global sales 2x US sales; launch 2025; assumes receives 15% royalty on sales, pays away 5% of revenue to Yale.
GDC-0084 milestones		5.1	1.04	Assumes potential licensing upfronts and milestones total $140m ($127m net of payments to Glioblast and Genentech; $38m after risk adjustment).
Cantrixil milestones		10.8	2.24	Assumes potential licensing upfronts and milestones total $140m ($23m after risk adjustment); assumes 5% of upfront and milestone payment paid away to Yale.
SG&A to 2020		-9.6	-1.98	
Portfolio total		**41.7**	**8.61**	
Cash (30 June 2017)		11.0	2.27	
Enterprise total		**52.7**	**10.88**	

Source: Edison Investment Research. Note: *Peak sales in actual dollars in forecast year. We assume that the addressable markets grow at 4% per year. Launch dates listed are calendar years (in some cases the launch will be in the following financial year to the calendar year stated).

We have also valued Kazia under an alternative accelerated approval scenario, which assumes a market launch in 2023 and that Kazia receives a higher 20% royalty rate and a larger $40m upfront payment because the data are ready for filing, with other deal terms the same as for the post-Phase III approval base case scenario. Exhibit 6 shows that accelerated approval for GDC-0084 would increase our valuation for Kazia to $96m (previously $108m) or $19.89/ADR (undiluted).

Exhibit 6: Kazia valuation in GDC-0084 accelerated approval scenario

	Likelihood (%)	rNPV ($m)	rNPV/ ADR ($)	Assumptions
GDC-0084 – GBM	25%	43.8	9.05	As per Exhibit 5, except 2023 launch (vs 2026) and 20% gross royalty on sales (vs 15%).
GDC-0084 – brain metastases in HER2+ breast cancer	20%	9.7	2.01	As per Exhibit 5, except 20% gross royalty on sales (vs 15%).
GDC-0084 milestones		11.7	2.42	Assumes potential licensing upfronts and milestones total $160m ($147m net of payments to Glioblast and Genentech; $48m after risk adjustment). Milestones received earlier than base case (final milestone in 2023 vs 2026).
GDC-0084 total		**65.2**	**13.47**	
Remainder of portfolio		20.1	4.14	
Portfolio total		**85.3**	**17.62**	
Cash (30 June 2017)		11.0	2.27	
Enterprise total		**96.3**	**19.89**	

Source: Edison Investment Research. Launch dates listed are calendar years.

Financials

We have updated our financial forecasts to reflect the out-licensing of Trilexium development and later timing of forecast spending on GDC-0084 clinical trials. We have reduced forecast R&D expenditure by 45% to $8.4m in FY18 and by 37% to $11.2m in FY18. Kazia had $11.5m cash at 30 June 2017, which we forecast will be sufficient to fund operations into FY19, by which time preliminary Cantrixil data are likely to read out. We estimate that the company may require $5m of additional funding in FY19 (part of the FY19 funding requirement could be met by upfront payments if Cantrixil is out-licensed at the completion of the Phase I trial). Note that we include unrisked clinical trial costs in our financial forecasts to show the potential funding requirement if the clinical trial program is conducted in line with our expectations (trial costs risk-adjusted for NPV calculation).

Exhibit 7: Financial summary

US$000s	2015	2016	2017	2018e	2019e
Year end 30 June	AASB	AASB	AASB	AASB	AASB
PROFIT & LOSS					
Sales, royalties, milestones	0	0	0	0	7,308
Other (includes R&D tax rebate)	1,293	2,896	6,765	3,141	3,399
Revenue	1,293	2,896	6,765	3,141	10,707
R&D expenses	(4,689)	(7,816)	(8,798)	(8,399)	(11,226)
SG&A expenses	(2,582)	(3,431)	(6,001)	(3,420)	(3,302)
Other	0	0	0	0	0
EBITDA	(5,978)	(8,352)	(8,034)	(8,678)	(3,822)
Operating Profit (before GW and except.)	(5,982)	(8,430)	(8,127)	(8,755)	(4,097)
Intangible Amortization	(450)	(1,043)	(52)	(1,006)	(926)
Exceptionals	882	(449)	0	0	0
Operating Profit	(5,550)	(9,923)	(8,179)	(9,761)	(5,022)
Net Interest	(221)	320	(407)	114	22
Profit Before Tax (norm)	(6,653)	(9,153)	(8,586)	(9,647)	(5,000)
Profit Before Tax (reported)	(5,772)	(9,602)	(8,586)	(9,647)	(5,000)
Tax benefit	0	0	157	0	0
Profit After Tax (norm)	(6,653)	(9,153)	(8,430)	(9,647)	(5,000)
Profit After Tax (reported)	(5,772)	(9,602)	(8,430)	(9,647)	(5,000)
Average Number of Shares Outstanding (m)	23.8	42.7	46.8	48.4	48.4
Average Number of ADRs Outstanding (m)	2.38	4.27	4.68	4.84	4.84
EPS - normalized (c)	(23.65)	(22.46)	(18.02)	(19.94)	(10.33)
EPS - diluted	(23.65)	(22.46)	(18.02)	(19.94)	(10.33)
Dividend per share (c)	0.0	0.0	0.0	0.0	0.0
Earnings per ADR - normalized (c)	(236.5)	(224.6)	(180.2)	(199.4)	(103.3)
Earnings per ADR - diluted (c)	(236.5)	(224.6)	(180.2)	(199.4)	(103.3)
Dividend per ADR (c)	0.0	0.0	0.0	0.0	0.0
BALANCE SHEET					
Fixed Assets	1,178	1,127	12,980	12,963	12,749
Intangible Assets	1,098	650	12,575	11,569	10,644
Tangible Assets	67	467	387	1,376	2,088
Investments	12	10	17	17	17
Current Assets	35,272	26,931	15,389	6,077	5,247
Stocks	0	0	0	0	0
Debtors	119	157	3,367	3,251	3,506
Cash	35,053	26,428	11,419	2,223	1,138
Other	100	346	603	603	603
Current Liabilities	(1,404)	(1,131)	(4,253)	(4,253)	(3,140)
Creditors	(1,279)	(1,027)	(1,479)	(1,479)	(365)
Short term borrowings	0	0	0	0	0
Other	(125)	(104)	(2,774)	(2,774)	(2,774)
Long Term Liabilities	0	(121)	(4,099)	(4,099)	(8,839)
Long term borrowings	0	0	0	0	(4,740)
Other long term liabilities	0	(121)	(4,099)	(4,099)	(4,099)
Net Assets	35,046	26,805	20,017	10,688	6,018
CASH FLOW					
Operating Cash Flow	(4,550)	(9,783)	(9,229)	(8,244)	(4,860)
Net Interest	0	320	196	114	22
Tax	0	0	0	0	0
Capex	(77)	(415)	(16)	(1,067)	(988)
Acquisitions/disposals	6	2	(5,607)	0	0
Equity Financing	37,458	618	(14)	0	0
Dividends	0	0	0	0	0
Other	0	0	0	0	0
Net Cash Flow	32,837	(9,258)	(14,670)	(9,196)	(5,825)
Opening net debt/(cash)	162	(35,053)	(26,428)	(11,419)	(2,223)
HP finance leases initiated	0	0	0	0	0
Other	2,379	632	(339)	0	0
Closing net debt/(cash)	(35,053)	(26,428)	(11,419)	(2,223)	3,602

Source: Novogen accounts, Edison Investment Research. Note: Solely for the convenience of the reader the financial summary table has been converted at a rate of US$0.76 to A$1. Novogen reports statutory accounts in Australian dollars. These translations should not be considered representations that any such amounts have been or could be converted into US dollars at the assumed conversion rate.

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